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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/297,703	07/19/1999	STEPHEN A. JOBLING	CASE#1637	1158

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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/297,703

Applicant(s)

JOBLING ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 February 2003 has been entered.
2. Claims 1-11, 16-27 and 32 have been cancelled and claims 33-59 have been added, as requested in Paper No.31, filed 19 February 2003. Claims 33-59 are pending.
3. There are two claims 59 in the amendment filed 19 February 2003, one located after claim 48 and one after claim 58. There was no claim 49. The first claim 59 has been renumbered claim 49.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

A sequence identifier is missing from the sequence in the last line of the paragraph spanning pg 18-19 in the substitute specification.

Sequence identifiers are missing from the Brief Description of Figures 2-6, 8-10 and 13.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules

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and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

6. The abstract is not descriptive of the instantly claimed invention, which is a cassava nucleic acid encoding a starch branching enzyme II, methods of using it to alter gene expression and to obtain starch with altered properties, and host cells and plants thereby obtained. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

7. The title of the invention is not descriptive of the instantly claimed invention, as above. A new title is required that is clearly indicative of the invention to which the claims are directed.

Note that titles can be up to 500 characters long.

Response to Amendment

8. The rejection of claims 1-2, 4 and 11 under 35 U.S.C. 102(b) as being anticipated by Fisher et al (1996, GenBank Accession No. U22428 and Plant Mol. Biol. 30:97-108), as it would apply to the instant claims, is WITHDRAWN in light of recitation in the instant claims that the nucleic acid is from cassava.

Claim Objections

9. Claims 34-35, 37-40, 42-46 and 49-56 are objected to because of the following informalities:

Claims 34-35, 37-40, 42, 44 and 49-56 start with an improper article.

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In claim 42, "further comprising" should be replaced with --wherein the nucleic acid further comprises--.

In claim 43, line 3, --wherein-- should be inserted before "said".

The comma after "43" in claim 46, line 3, should be deleted.

Claim 45 has an improper article before "nucleic" in line 1.

In claim 46, --wherein-- should be inserted before "said" in line 5.

The comma after "acids" in claim 50, line 2, should be deleted.

In claim 50, --wherein-- should be inserted before "said" in line 4.

Articles are missing before the cells in claims 49 and 54. Alternately, the claims may be amended to insert -- from a plant -- after "is" in line 1 and to replace the list of cells with a list of plants.

Claim Rejections - 35 USC § 112

10. Claims 36-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is directed to a specific *E. coli* strain. Since the *E. coli* strain is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the *E. coli* strain is not so obtainable or available, a deposit of the strain may satisfy the requirements of 35 USC 112. The specification does not

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disclose a repeatable process to obtain the strain and it is not apparent if the strain is readily available to the public. Thus, a deposit is required for enablement purposes.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

11. Claims 41 and 43-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated cassava nucleic acids with 88% identity to SEQ ID NO:28 and encoding SBEII, and nucleic acids encoding SEQ ID NO:29, methods of using those nucleic acids to alter starch properties in cassava, and plants transformed with those nucleic acids, does not reasonably provide enablement for methods of using those nucleic acids to alter starch properties in other plants, nor for nucleic acids encoding effective portions of SEQ ID NO:29, or for 300-600bp long nucleic acids that have 88% identity to SEQ ID NO:28 and encode SBEII, methods of using those nucleic acids, and plants transformed with those nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with

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these claims. The rejection is modified from the rejection set forth in the Office action mailed 16 May 2002, as applied to claims 1-2, 4-8, 11, 16-27 and 32. Applicant's arguments filed 19 February 2003 and the Declaration of Joseph Emling, filed 18 November 2002, have been fully considered but they are not persuasive.

The claims are drawn to cassava nucleic acids with 88% identity to SEQ ID NO:28 and encoding SBEII, nucleic acids encoding SEQ ID NO:29, nucleic acids encoding effective portions of SEQ ID NO:29, and 300-600bp long nucleic acids that have 88% identity to SEQ ID NO:28, methods of using those nucleic acids to alter starch properties in any plant, and optionally further comprising transformation with other nucleic acids that interfere with genes in the cell, and plants so transformed.

The specification, however, only teaches two cassava nucleic acids with 88% identity to SEQ ID NO:28 and encoding SBEII, methods of using those nucleic acids to alter starch properties in cassava, and plants transformed with those nucleic acids.

The specification does not provide guidance for nucleic acids encoding effective portions of SEQ ID NO:29, or for 300-600 bp long nucleic acids that have 88% identity to SEQ ID NO:28 and encode SBEII, methods of using those nucleic acids, and plants transformed with those nucleic acids. The specification also does not provide guidance for other nucleic acid that interfere with the expression of genes in cassava or other plants, including portions of the cassava SBEI gene effective to interfere with the expression of that gene in cassava.

The specification provides no guidance for which portions of SEQ ID NO:29 would be effective to complement the mutation in KV832 or for any 300-600 bp long nucleic acids than encode proteins with SBEII activity.

As discussed in previous Office actions, antisense constructs that are not completely homologous to the target gene are generally ineffective. Colliver et al showed that transformation of bird's foot trefoil with a construct that was antisense to bean chalcone synthase resulted in transformants with *increased* levels of chalcone synthase transcripts (pg 519, left column, paragraph 2) and note other instances when this phenomenon has occurred (pg 519, right column, paragraph 1). The specification does not teach how to overcome this problem or teach any cassava nucleic acid that has 88% identity to SEQ ID NO:28 and that inhibits the expression of SBE II in any plant other than cassava.

The specification does not teach portions of the cassava SBE I gene that can be used to inhibit expression of that gene.

Applicant urges that the specification teaches the discovery of two cassava genes that encode proteins with SSB II activity, SBE and complementation assays, and sense and antisense inhibition of genes. Applicant points to the Declaration of Joseph Emling, who teaches that cassava plants transformed with an SBEII cDNA in an antisense orientation produced starch with altered properties in the form of increased viscosity (response pg 8-10).

This is not found persuasive because the rejection is no longer over isolated cassava nucleic acids with 88% identity to SEQ ID NO:28 and encoding SBEII, and nucleic acids encoding SEQ ID NO:29, methods of using those nucleic acids to alter starch properties in cassava.

12. Claims 41 and 43-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 16 May 2002, as applied to claims 1-2, 4-8, 11, 16-27 and 32, due to amendment. Applicant's arguments filed 19 February 2003 have been fully considered but they are not persuasive.

The claims are drawn to nucleic acids encoding effective portions of SEQ ID NO:29. The claims are also drawn to 300-600 bp long cassava nucleic acids that have 88% identity to SEQ ID NO:28 and to cassava nucleic acids that have 88% identity to SEQ ID NO:28 that inhibit the expression of SBEII in any plant other than cassava.

The claims are also drawn to methods of using any nucleic acid that interferes with the expression of a gene, including methods of so using fragments of the cassava SBEI gene.

In contrast, the specification only describes cassava nucleic acids that have 88% identity to SEQ ID NO:28. Applicant does not describe other DNA molecules encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided. The specification also does not describe phenotype of the plants produced by the method.

Hence, Applicant has not, in fact, described the nucleic acids or the methods within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

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See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997) at pg 1406:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

... A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

... the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

Applicant urges that the specification teaches the discovery of multiple novel genes encoding SBE, and the currently pending claims are directed to these nucleic acids (response pg 10-11).

This is not found persuasive because the claims are also drawn to fragments of SEQ ID NO:29 and of nucleic acids that have 88% identity to SEQ ID NO:29. The specification does not describe such fragments that have SBEII activity, that complement the KV832 mutation, or that inhibit gene expression.

Applicant urges that "effective portion" is explicitly defined on pg 3 of the specification, and the claims have been amended to include that definition (response pg 10).

This is not found persuasive for the reasons discussed above.

13. Claims 33-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 16 May 2002, as applied to claims 1-2, 4-8, 11,

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16-27 and 32, due to amendment of the claims. Applicant's arguments filed 19 February 2003 do not apply to these rejections.

Claims 33-41 are indefinite in their recitation of "and its complement". Claiming two products is improper; products should be claimed in the alternate. It is suggested that "and" be replaced with --or--.

Claim 41 is indefinite in its recitation of "and the amino acid sequence of SEQ ID NO:29". Does the nucleic acid encode an effective portion **and** SEQ ID NO:29? Does the phrase apply instead to the polypeptide? If the latter, the phrase "a polypeptide having ... activity and " is unnecessary, because SEQ ID NO:29 already has SBE II activity.

Claim 42 is indefinite in its recitation of "further comprising". It is not clear if Applicant intends to claim a cassava nucleic acid that encodes SEQ ID NO:29 and comprises native 5' and/or 3' untranslated regions, or if Applicant intended to claim a construct comprising the isolated nucleic acid of claim 34 operably linked to 5' and/or 3' untranslated regions.

It is not clear in claims 43 and 58 what the phrase "operably linked" modifies- -SEQ ID NO:28? nucleic acid?. By position in the claims, it modifies "SEQ ID NO:28". If Applicant intends the phrase to modify "nucleic acid", a nucleic acid from cassava would not be operably linked in the antisense orientation to a promoter and would not be linked to any plant promoter, only to its native one. It is suggested that claim 43 be drawn to a construct comprising a nucleic acid from cassava operably linked in the sense or anti-sense orientation to a promoter operable in plants, wherein the nucleic acid has at least 88% sequence identity to SEQ ID NO:28 and wherein the nucleic acid encodes a protein with SBE II activity, and that claim 58 be drawn to a plant comprising such a construct.

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In claims 46 and 50 it is not clear what the practitioner of the invention does to cause transcription of the introduced nucleic acid, as the methods do not use a promoter, like an inducible one, that would require action on the part of the practitioner.

It is suggested that in claims 46 and 50 "being sufficient to" in lines 4 and 5, respectively, be deleted.

Claim 46 lacks antecedent basis for the limitation "the introduced nucleic acid" in line 4.

Claim 47 lacks antecedent basis for the limitation "the altered host cell" in line 1.

In claims 52-53 it is suggested that "effective to interfere" be replaced with --that interfere--.

Claim 55 lacks antecedent basis for the limitation "the altered host cell" in line 2.

Claim 56 lacks antecedent basis for the limitation "the altered host cell" in lines 1-2.

Claim 57 appears to be missing at least one word in the phrase "an altered host cell according to the method of claim 56". Should --produced-- be inserted after "cell"?

14. Claims 33-59 are free of the prior art, given the failure of the prior art to teach or suggest isolated cassava nucleic acids having 88% identity to SEQ ID NO:29 and methods use.

15. Claim 33 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

16. Claims 34-35 and 42 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and the objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Conclusion

17. No claim is allowed.


18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.

May 20, 2003

A handwritten signature in cursive script, appearing to read "Amy Nelson".

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